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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/691,633

10/22/2003

Michael D. West

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04/14/2006

PERKINS COIE LLP

P.O. BOX 2168

MENLO PARK, CA 94026

EXAMINER

LEWIS, PATRICK T

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 04/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/691,633	WEST ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Patrick T. Lewis	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 February 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 28,30-33 and 35-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28,30-33 and 35-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Applicant's Response Dated February 16, 2006***

1. Claims 28, 30-33, and 35-51 are pending. An action on the merits of claims 28, 30-33, and 35-51 is contained herein below.
2. The rejection of claims 29 and 34 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement has been rendered moot in view of the applicant's amendment dated February 16, 2006.
3. The rejection of claims 28, 30-33, 35-45 and 47-51 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is maintained for the reasons of record as set forth in the Office Action dated August 1, 2005.
4. The rejection of claims 29 and 34 under 35 U.S.C. 112, first paragraph, scope of enablement, has been rendered moot in view of the applicant's amendment dated February 16, 2006.
5. The rejection of claims 28, 30-33 and 35-51 under 35 U.S.C. 112, first paragraph, scope of enablement, is maintained for the reasons of record as set forth in the Office Action dated August 1, 2005.

### ***Rejections of Record Set Forth in the Office Action Dated August 1, 2005***

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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7. Claims 28, 30-33, 35-45 and 47-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

8. Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims obviates the rejection of record. Applicant should note that simply grouping the response(s) to the rejections together as one is not sufficient. The Office Action dated August 1, 2005 set forth two distinct rejections under 35 U.S.C. 112, first paragraph, and that the requirements under the law for said rejections are different.

As set forth in the Office Action dated August 1, 2005, a functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. It is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials, and to describe how to obtain it. Functional descriptions of chemical compounds/compositions must be coupled with a known or disclosed correlation between function and structure. An adequate written description of a chemical invention also requires a precise definition such as by structure, formula, chemical name, or physical properties, and not merely a wish or plan for obtaining the chemical invention claimed.

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Applicant should note that claim 46 has not been rejected for failing to comply with the written description requirement.

9. Claims 28, 30-33 and 35-51 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inhibiting proliferation of immortalized, mammalian cells which have telomerase by administering an effective amount of GTO-12 to the cell, does not reasonably provide enablement for a method of inhibiting proliferation of immortalized, mammalian cells which have telomerase by administering a compound other than GTO-12. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

10. Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims obviates the rejection of record. Applicant should note that simply grouping the response(s) to the rejections together as one is not sufficient. The Office Action dated August 1, 2005 set forth two distinct rejections under 35 U.S.C. 112, first paragraph, and that the requirements under the law for said rejections are different.

As set forth in the Office Action dated August 1, 2005 undue experimentation is required to determine which compounds would be useful as an inhibitor of telomerase to use for inhibiting the proliferation of various immortalized mammalian cells for which the instant invention is applicable. There has not been provided adequate guidance in the written description for accomplishing such, as only a limited number of nucleoside

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analogues were assessed, out of the numerous nucleoside and nucleotide analogues known in the art, not to mention the near infinite number of other known compounds and classes of compounds. While it is noted that an assay has been described for identifying other telomerase inhibitors, without guidance as to what molecules would likely effect telomerase activity, undue trial and error experimentation would be required to screen through the myriad of different chemical molecules to determine those with the desired telomerase inhibiting activity and that would function in the claimed method of inhibiting cellular proliferation.

It is noted that there is a great deal of unpredictability in the art. For example, various nucleoside and nucleotide analogues are known as inhibitors of polymerases such as reverse transcriptase, however, not all nucleoside and nucleotide analogues are inhibitors of polymerases. Further, there is no discernable pattern as to which nucleoside and nucleotide analogue will inhibit a specific polymerase, such as reverse transcriptase, and in particular telomerase. The art at the time the invention was made fails to establish predictability with regard to the properties of the nucleosides and nucleotides analogues needed to perform the methods as instantly claimed. Greider et al. NATURE, 1989, Vol. 337, pages 331-336 (Greider) is representative of the state of the art at the time of the invention. Greider teaches the inhibition of telomerase activity by oligonucleotide 3 in either the presence or absence of RNase H; however, oligonucleotide 3 was the only nucleic acid assessed which showed inhibition of telomerase activity.

It is noted that while there are some working examples using certain nucleoside analogs, it is not seen as sufficient to support the breadth of the claims. The instant specification is not seen to provide adequate guidance which would allow the skilled artisan to extrapolate from the disclosure and examples provided to enable the use of any other nucleoside analog, let alone a non-nucleoside analog, to inhibit telomerase activity in an immortalized mammalian cell. It is noted that Law requires that the disclosure of an application shall inform those skilled in the art how to use applicant's alleged discovery, not how to find out how to use it for themselves. See *In re Gardner* et al. 166 USPQ 138 (CCPA 1970).

#### **Conclusion**

11. Claims 28, 30-33, and 35-51 are pending. Claims 28, 30-33, and 35-51 are rejected. No claims are allowed.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### **Contacts**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 571-272-0655. The examiner can normally be reached on Monday - Friday 10 am to 3 pm (Maxi Flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Dr. Patrick T. Lewis  
Primary Examiner  
Art Unit 1623

ptl